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EXAMINER

FOX, DAVID T

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 01/16/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/377,502

Applicant(s)

Paul et al

Examiner

FOX

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

- 3 -

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 10/23/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-49 is/are pending in the application.
- Of the above claim(s) 6, 33 and 35 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-5, 7-32, 34, 36-49 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 23
- ☒ Interview Summary, PTO-413 - #19, 20
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 October 2002 has been entered.

Applicants' statements on page 3 of the amendment of 23 October 2002 have been interpreted in light of the telephonic interview of 2 October 2002 (see page 2 of paper no. 20, middle paragraph) as a request to shift prosecution from previously elected (in the response filed 17 January 2001) species I to species II, namely chimeric gene constructs encoding ribonuclease subunits for the production of male sterile plants. The election of species requirement was originally set forth in the Office actions mailed 13 December 2000 and 23 March 2001. Accordingly, claims 1-5, 7-32, 34 and 36-49, drawn to species II, are hereby examined. Claim 6, newly limited to previously elected species I, and claims 33 and 35, drawn to non-elected species III, are withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 21 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 7 and 21 are indefinite in their recitation of "such as" as it is unclear whether the subsequently recited claim elements are merely exemplary or are required claim elements.

Claim 25 is indefinite in its recitation of "the tissue-specific promoter" which lacks antecedent basis in claim 15 from which it depends. Amendment of claim 25 to change its dependency to claim 19 would obviate this rejection.

Claims 13, 20 and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 13 and 27 are broadly drawn to genes of any sequence or length and from any source encoding any protein dimerization domain of any sequence or length from any protein of any sequence or activity. Claim 20 is broadly drawn to genes encoding naturally occurring subunits, of any length or sequence, of any polypeptide of any sequence or biological activity, from any organism. In contrast, the specification provides no guidance for even a single protein dimerization domain, or for any protein which can be split into naturally occurring subunits, for genes encoding them, or for the use of genes encoding either of these peptides in a method to transform plants.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter

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sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991), where it is taught that a gene is not reduced to practice until the inventor can define it by “its physical or chemical properties” (e.g. a DNA sequence).

Claims 1-5, 7-10, 12-24, 26-32, 34 and 36-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a pair of plants each containing at least one gene encoding a subunit of a ribonuclease wherein at least one of the

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genes comprises a tapetum-specific promoter operably linked to the subunit-encoding sequence, does not reasonably provide enablement for claims broadly drawn to the use of any type of promoter including constitutive promoters for both subunit-encoding constructs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to pairs of plants of any species which each comprise a gene comprising any promoter of any type ligated to any sequence encoding any subunit of any length or sequence of any ribonuclease of any length or sequence, wherein said plants can be crossed to generate a male-sterile plant containing both subunits of the ribonuclease, and seeds of said plants. The claims are also broadly drawn to the use of a multitude of tissue-specific promoter types, including those specific for roots or seeds, for the production of viable male sterile plants and seeds thereof. In contrast, the specification only provides guidance for the obtention of viable, male-sterile plants or seeds thereof following the crossing of two plants which each comprise a chimeric gene encoding a subunit of a ribonuclease, wherein at least one of the chimeric genes comprises a tapetum-specific (male tissue-specific) promoter. No guidance is provided for any other tissue-specific promoter, or for any constitutive promoter (expressed in all the cells and tissues of a plant) which when present in both genes would not lead to complete loss of plant or seed viability.

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The production of viable plants containing a complete ribonuclease expressed under the control of a constitutive promoter, i.e. expressed in all cells and tissues, is unpredictable and unlikely. See, e.g., Gutterson et al (U.S. 6,392,119), column 26, lines 1-35, especially lines 32-35; column 34, lines 25-67; and columns 35-36, lines 1-10), who teach that the expression of genes encoding both units of a split ribonuclease under the control of a constitutive promoter results in failure to produce viable seed as well as cell and tissue death, thus failing to produce whole plants regenerated from the tissue.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify, isolate and evaluate a multitude of non-exemplified tissue-specific promoter types for their ability to effect male sterility; or to obtain and evaluate successful production of viable plants and seeds following the crossing of two plants each containing a gene encoding a subunit of a ribonuclease under the control of a constitutive promoter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b).

Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5, 7-8, 10-11, 14-19, 21-22, 24-25, 28-32, 34, 36-40, 43 and 46-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Gutterson et al (U.S. 6,392,119 effectively filed 24 January 1997).

The claims are broadly drawn to a pair of plants each comprising a heterologous gene comprising a sequence encoding a portion of a ribonuclease, wherein the ribonuclease includes barnase or Rnase A, including two barnase subunits split at amino acid residues 35 or 36, wherein at least one of the heterologous genes is under the control of a tapetum-specific promoter, wherein crossing of the two plants produces male-sterile plants and seeds thereof.

Gutterson et al teach a pair of plants each comprising a heterologous gene comprising a sequence encoding a portion of a barnase, including two subunits split at amino acid residues 35 or 36, wherein at least one of the heterologous genes is under the control of a tapetum-specific promoter, wherein crossing of the two plants produces male-sterile plants and seeds thereof (see, e.g., column 17, lines 44-54; column 23, lines 22-63; column 24, especially lines 59-67; column 25; and column 27, lines 15-35). Gutterson et al also suggest the use of the RNase A gene split into two subunits at the 20th amino acid residue (see, e.g., column 13, lines 30-39).

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Since the effective U.S. filing date of the instant application is more than 3 months after the effective filing date of the patent, 37 CFR 1.608(b) requires that the applicant must file (1) evidence, such as patents, publications and other documents, and one or more affidavits or declarations which demonstrate that applicant is *prima facie* entitled to a judgement relative to the patentee, and (2) an explanation stating with particularity the basis upon which the applicant is *prima facie* entitled to the judgement. The patent cannot be overcome by an affidavit or declaration under 37 CFR 1.131 but only through interference proceedings. See MPEP 2308.01.

Claims 9 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gutterson et al (U.S. 6,392,119 effectively filed January 1997).

The claims are broadly drawn to plants homozygous for at least one heterologous gene encoding at least one subunit of a ribonuclease, and methods of crossing them to obtain male sterile plants.

Gutterson et al teach plants transformed with at least one heterologous gene encoding at least one subunit of a ribonuclease, and methods of crossing them, as discussed above, but do not explicitly teach the use of plants homozygous for the gene.

It would have been obvious to one of ordinary skill in the art to utilize the method of crossing plants to obtain male-sterile plants as taught by Gutterson et al, and to modify that method by selecting for parents which are homozygous for the heterologous gene, given the recognition by those of ordinary skill in the art of the advantages of 100% gene transmission by a parent homozygous for the gene, thereby increasing the efficiency of the crosses, and given the

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availability to those of ordinary skill in the art of selfing techniques and selection techniques for obtaining and selecting plants homozygous for a particular gene.

Claims 12, 13, 20, 26, 27, 41, 42, 44 and 45 are deemed free of the prior art, given the failure of the prior art to teach or suggest plants comprising a gene encoding a ribonuclease subunit linked to a targeting sequence or a dimerization domain, or the use of genes encoding naturally divided ribonuclease subunits.

No claim is allowed.

Claims limited to a pair of plants each comprising a heterologous gene encoding a portion of the RNaseA protein, wherein the N-terminal portion consists of amino acid residues 1-15, would also be free of the prior art.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Goff et al (U.S. 5,880,333 effectively filed March 1995) and Bennett et al (U.S. 5,801,027 effectively filed May 1995) are pertinent to non-elected Species I. At least Goff et al appears to teach plants containing heterologous genes each encoding a subunit of a regulatory protein, wherein expression of both subunits in a single plant leads to alterations in plant phenotype.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

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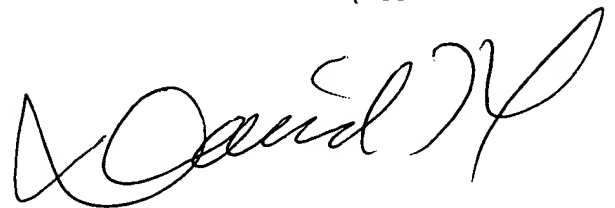
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

January 7, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", written over the printed name and title.